

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,389	11/10/2003	Narayanan Sundararajan	21058/1206459-US2	4354
7278 DARDY 6 DA	7590 10/02/2007		EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770			SISSON, BRADLEY L	
Church Street Station New York, NY 10008-0770			ART UNIT	PAPER NUMBER
			1634	
			MAIL DATE	DELIVERY MODE
	•		10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Commence	10/705,389	SUNDARARAJAN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Bradley L. Sisson	1634				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>23 August 2007</u> .  2a)□ This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  3)□ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)  Claim(s) 46-85 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) 46-85 is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the d Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examiner	pted or b) objected to by the E rawing(s) be held in abeyance. See on is required if the drawing(s) is obje	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119	•					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)	4) Interview Summary (Interview	e				
Paper No(s)/Mail Date	6)					

Application/Control Number: 10/705,389 Page 2

Art Unit: 1634

## DETAILED ACTION

## Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 August 2007 has been entered.

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Page 3

Art Unit: 1634

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 5. Claims 46-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,280,939 B1 (Allen) in view of US Patent 6,194,144 B1 (Köster) and US Patent 6,635,452 B1 (Monforte et al.).
- 6. Allen discloses a method of sequencing DNA or RNA by use of a cantilever (column 5). As seen therein, a polymerase is used to incorporate nucleotides into a nascent strand of nucleic acid. As a result of mass changes, and movement of the polymerase, the frequency of the cantilever is changed. The frequency of the cantilever is monitored through a variety of means, including electron resistance, and the sequence of the nucleic acid is determined.
- 7. Allen, column 8, discloses the method being used to detect mutations in nucleic acids.
- 8. Allen has not been found to teach augmenting the changes in mass, nor use of 3' bl3ocking groups.
- 9. Köster teaches at length of incorporating mass-modifying labels into the nucleotides that are being incorporated into a nascent strand, and that by using mass-modifying labels, one is better able to identify the nucleotides that are incorporated, and therein, the sequence of the nucleic acid.
- 10. Monforte et al., disclose a plethora of mass-modifying labels and their use in allowing for the identification of nucleotides. As seen in Fig. 5, the strand can comprise a blocking group at

Application/Control Number: 10/705,389

Art Unit: 1634

the 3'. At column 5, Monforte et al., disclose that the mass label may be attached through a releasable attachment.

Page 4

- 11. Monforte et al.,, column 7, disclose that each probe (applicant's nucleotide), may have a different label, thereby allowing for specific identification/detection.
- 12. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the procedure of Allen with that of Köster as the use of mass-modifying labels enhances the accuracy and speed of the nucleic acid sequencing reaction. Said artisan would have also been motivated to have incorporated mass labels, and a 3' blocking group, as disclosed by Monforte et al.,, as such would have allowed for the accurate identification of the incorporated nucleotide prior to the incorporation of the next nucleotide. By being able to use a reversible label, as well as a reversible blocking group, the artisan has better control over the rate and accuracy of the assay.
- 13. In view of the detailed disclosure, and the direct application of known technology to solve art-recognized needs, the ordinary artisan would have been high motivated and would have had a most reasonable expectation of success.
- 14. Attention is directed to the decision in KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

15. For the above reasons, and in the absence of convincing evidence to the contrary, claims 46-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,280,939 B1

Application/Control Number: 10/705,389 Page 5

Art Unit: 1634

al.).

(Allen) in view of US Patent 6,194,144 B1 (Köster) and US Patent 6,635,452 B1 (Monforte et

Conclusion

16. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/ Primary Examiner Art Unit 1634

BLS